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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,565	10/28/2003	Isaac Farr	200313766-1	9174

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EXAMINER

LAMBELET, LAWRENCE EMILE

ART UNIT PAPER NUMBER

1732

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/695,565	Applicant(s) FARR ET AL.	
	Examiner Lawrence Lambelet	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-12, in the reply filed on 8/19/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim reads, in part, "at least one component selected from at least one filler and at least one multivalent cation". As written, a multivalent cation, for example, might not be the one component selected, and this omission would contradict the disclosure in the specification at lines 31-32 on page 5, wherein both filler and cation elements appear to be required. Examiner recommends the phrasing: "At

least one component selected from a filler and at least one component from a multivalent cation”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo et al (U.S. Patent Application Publication 2002/00157280), and further in view of Schulman et al (U.S. Patent 6,808,659).

Payumo et al, hereafter “Payumo”, discloses a method of producing a structure, in this case an oral dosage form, as recited by claim 1. Payumo teaches the Solid Free-form Fabrication (SFF) technique of forming a three-dimensional object through successive layer depositions of powder and binder as shown in paragraph [0021]. Payumo further teaches that the powder may contain particles of binder in solid form and that the binder may include sodium alginate. In other words, an alginate-based powder is provided in the combined teachings of paragraphs [0026] and [0046]. The object thus formed with alginate-based material will have elastomeric (flexible) properties, by applicant’s admission. See lines 5-6 on page 3 of the instant specification.

Payumo teaches that the powder includes cellulose (filler) in addition to the alginate compound, as required by claim 2. See paragraph [0024].

Payumo teaches laying down a layer of powder and dispensing liquid (binder) onto predetermined regions of the powder bed, as required by claims 3, 4, and 5. See paragraph [0021].

Payumo teaches that the binder may include acrylic acid polymers (water retaining additive), as required by claim 6. See paragraph [0046].

Payumo teaches that the alginate compound is sodium alginate, as required by claim 7. See paragraph [0046].

Payumo teaches that the binder is aqueous-based (water constituting swelling agent), as required by claim 8. See paragraph [0046].

Payumo teaches that the binder may include polyethylene oxide (viscosity modifier), as required by claim 9. This is shown in paragraph [0046]. It would have been obvious to one of ordinary skill to alternatively mix polyethylene oxide in the powder, as required by claim 10. Absent new or unexpected results, any order of performing process steps, in this case mixing, is *prima facie* obvious. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946).

Payumo teaches that the sodium alginate can be in both the binder and the powder, as discussed above for claim 1. The percentage allocation of alginate-based material between the binder and powder forms would appear to be a matter of arbitrary, and therefore obvious, choice for one skilled in the art. A 50% by weight allocation to

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the powder and 50% to the binder, for example, would satisfy the requirement of claim 11.

Payumo does not teach the powder composition including a multivalent cation, as required by claim 2. Payumo further does not teach the multivalent cation in a range of about 0.01% to 50% by weight, or the filler in a range of 5% to 90% by weight, or the alginate compound in a range of 10% to 95% by weight, of the powder mixture, as required by claim 12.

Schulman et al, hereafter "Schulman", teaches that calcium phosphate (multivalent cation) is used as a filler at lines 14-29 in column 7. Schulman further teaches that the filler is up to 30% by weight of the composition. Since calcium phosphate functions as both cation and filler, the range satisfies the claim and leaves at least 70% balance for the alginate compound.

Payumo and Schulman are combinable because they are concerned with a similar technical field, namely SFF. It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Payumo the powder ingredient yielding a multivalent cation, as taught by Schulman. The motivation would have been to simplify the process by combining filler and cation functions into a single material.

Conclusion

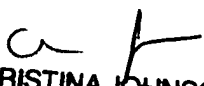
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Lambelet whose telephone number is 571-272-1713. The examiner can normally be reached on 8 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEL
9/19/2006


CHRISTINA JOHNSON
PRIMARY EXAMINER
9/20/06